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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,936	05/31/2000	Michael G. Kahn M.D. Ph.D	FSTK 1000-0	5001

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	
MAIL DATE	DELIVERY MODE
02/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/584,936	KAHN M.D. PH.D ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5, 7- 30, 36, 45-109, 118, 137, 139 and 140* is/are pending in the application.

4a) Of the above claim(s) *7,12-30,36,45-109,118 and 137* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-11,139 and 140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20081201*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 12/1/08. Claims 1 and 4 have been amended. Claims 1-5, 8-11, and 139-140 are rejected.

Claim Objections

2. The objection to claims 1 and 4 is hereby withdrawn due to the amendment filed 12/1/08.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 4, 10, 11, and 139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Gillings et al. (5,666,490).

(A) Referring to claim 1, Colon discloses at least one computer readable medium collectively carrying a machine readable database identifying (abstract of Colon):

first patient eligibility criteria for a first clinical trial protocol (col. 6, lines 39-42 of Colon); and

a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow tasks to be performed for a particular patient (col. 6, line 39 – col. 7, line 10 of Colon).

Colon does not disclose wherein the post-enrollment workflow tasks include at least one element of the group consisting of a post-enrollment instruction to have a specified test performed on the patient, and a post-enrollment instruction to have a specified case report form completed for the patient.

Gillings discloses wherein the post-enrollment workflow tasks include a post-enrollment instruction to have a specified case report form completed for the patient (col. 5, lines 12-30 of Gillings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Gillings within Colon. The motivation for doing so would have been to better manage clinical trial data (col. 1, lines 65-67 of Gillings).

Insofar as the claim recites "at least one element of the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 2, Colon discloses wherein said database further identifies preliminary patient eligibility criteria applicable to said first clinical trial protocol (col. 2, lines 5-8 of Colon).

(C) Referring to claim 4, Colon does not disclose wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified case report form completed for the patient.

Gillings discloses wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified case report form completed for the patient (col. 5, lines 12-30 of Gillings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Gillings within Colon. The motivation for doing so would have been better manage clinical trial data (col. 1, lines 65-67 of Gillings).

(D) Referring to claim 10, Colon discloses wherein said first plurality of workflow tasks include an instruction to enroll a patient into a clinical trial (col. 5, lines 25-35 of Colon).

(E) Referring to claim 11, Colon discloses wherein said first plurality of workflow tasks include an instruction to enroll a patient into a clinical trial (col. 5, lines 25-35 of Colon).

(F) Referring to claim 139, Colon discloses wherein said post-enrollment workflow tasks include patient management tasks (col. 6, lines 1-14 of Colon).

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Gillings et al. (5,666,490), and further in view of Cimino ("Distributed cognition and knowledge-based controlled medical terminologies").

(A) Referring to claim 3, Colon and Gillings do not disclose wherein said database identifies a term by reference to a controlled medical terminology database.

Cimino teaches that controlled medical terminologies (CMTs) are at the heart of most medical systems (pages 154 & 162 of Cimino).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cimino within Colon and Gillings. The motivation for doing so would have been to enable data sharing and coordination of multiple applications (page 161 of Cimino).

6. Claims 5 and 140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Gillings et al. (5,666,490), and further in view of Coli et al. (6,018,713).

(A) Referring to claims 5 and 140, Colon and Gillings do not disclose wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient.

Coli discloses wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient (col. 4, line 62 - col. 5, line 31 of Coli).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Coli within Colon and Gillings. The

motivation for doing so would have been to enhance communication by providing the ability to order necessary medical tests (col. 4, lines 52-61 of Coli).

7. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Gillings et al. (5,666,490), and further in view of McAlindon et al. (US 7,251,609 B1).

(A) Referring to claims 8 and 9, Colon and Gillings do not disclose wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before an instruction to obtain informed consent and wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

McAlindon discloses wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before an instruction to obtain informed consent and wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent (col. 4, lines 37-45 and col. 5, lines 5-25 of McAlindon).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of McAlindon within Colon and Gillings. The motivation for doing so would have been to gather the necessary information and follow the procedures in order to allow the candidate to participate in the clinical trial (col. 5, lines 5-25 of McAlindon).

Response to Arguments

8. Applicant's arguments filed 12/1/08 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 12/1/08.

(1) Applicant argues that Gillings' database does not include any instructions to complete a CRF. It contains CRFs, which is to be expected of a typical electronic document management system, but does not contain any instructions for the clinician to have one completed.

(2) Applicant argues that there does not appear to be any instruction in Colon's database, to perform the process of enrolling the patient.

(3) Applicant argues that Cimino does not appear to even mention clinical trials, much less suggest that CMTs can be used in a database that identifies widely disparate features of a clinical trial protocol. The Examiner's citation to Cimino p. 161 as motivating such a combination is to no avail because there Cimino was speaking of patient care applications, not clinical trial protocols.

(4) Applicant argues that Coli fails to teach a database identifying a workflow task for a clinical trial protocol, as called for in Applicants' claim. Nor does it teach that such a database identify a post-enrollment task for such a protocol, and certainly not a database that identifies a post-enrollment workflow task that includes a post-enrollment instruction to have a specified test performed on a patient.

(5) Applicant argues that McAlindon does not teach the instruction in a workflow task identified by a database. Applicant also argues that McAlindon is not prior art.

(A) As per the first argument, the Examiner respectfully submits that the broadest reasonable interpretation of an "instruction to have a specified case report form completed" would include the routing of the case report form to the appropriate individuals for data entry, which is disclosed by Gillings (see col. 5, line 60 – col. 6, line 46 of Gillings).

Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., instructions for the *clinician* to complete the CRF) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(B) As per the second argument, the Examiner respectfully submits that Applicant fails to fully consider the reference. Colon teaches an eligibility routine that determines whether the patient qualifies for the clinical study (see col. 2, lines 5-19 and col. 6, lines 39-64 of Colon). Colon's system "efficiently makes the assignments in a quick and efficient manner…." (the Examiner interprets the "assignment" to be a form of "enrolling"; see col. 1, lines 43-58 of Colon).

(C) In response to applicant's argument that Cimino does not appear to even mention

clinical trials, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(D) As per the fourth argument, the Examiner respectfully submits that Coli was relied upon to teach the limitation of a "post-enrollment instruction to have a specified test performed on the patient." Coli teaches the ordering/requesting of lab tests (see col. 4, line 51 - col. 5, line 31 of Coli). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, the language of claim 1 requires that only one of the limitations from the Markush group be selected and addressed by the prior art. Limitation B has been addressed by the Gillings reference.

Claims 5 and 140 further define alternate limitations of claim 1, which are not required, in light of the current claim language. As such, even though the Examiner applied additional art (i.e., Coli), no additional art is required to address the limitations of claims 5 and 140.

(E) As per the fifth argument, the Examiner respectfully submits that McAlindon was relied upon to teach the features related to obtaining informed consent (see pages 21, 37, 28, 44, 54, and 50 of provisional application 60/131,528). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 - 6:00 .

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./
Examiner, Art Unit 3686
ln
2/13/09

/Gerald J. O'Connor/
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